REMARKS

Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66 and 72-113 are pending. Further, independent claims 1, 12, 22, 32, 42, 52, and 62 have been amended. Claims 77, 83, 89, 95, 101, 107, and 113 are cancelled without prejudice to or disclaimer of the underlying subject matter. Claims 7-11, 17-21, 27-31, 37-41, 47-51, 57-61, and 67-71 were previously cancelled without prejudice to or disclaimer of the underlying subject matter. Support for the foregoing amendments can be found throughout the specification and claims as originally filed, for example at page 3, lines 2-26. Upon entry of the amendment, claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72-76, 78-82, 84-88, 90-94, 96-100, 102-106, and 108-112 will be pending. No new matter enters by way this amendment.

I. Restriction Requirement

Applicants acknowledge the finality of the restriction requirement, but maintain their traversal as set forth in Applicants' Response to Restriction/Election Requirement filed May 5, 2005. However, to facilitate prosecution non-elected claims 77, 83, 89, 95, 101, 107, and 113 have been cancelled without prejudice to or disclaimer of the underlying subject matter.

II. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 76, 78, 82, 84, 88, 90, 94, 96, 100, 102, 106, 108, and 112 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Office Action at page 2. Applicants respectfully disagree.

The Examiner alleges that the use of the word "or" in the phrase "capable of binding to or activating a GLP-1 receptor in vivo" "implies that the claims embrace the use of peptide compounds which are capable of binding to but not necessarily activating GLP-1, e.g., embrace the use of GLP-1 antagonists." Office Action at page 2. The Examiner further argues that "there is no original disclosure of the use of GLP-1 antagonists to treat subjects suffering from PCOS." *Id.* Applicants traverse for at least the following reasons.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972). All that is required is that a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996). The skilled artisan would recognize that Applicants were in possession of the invention as now claimed at the time of filing.

Applicants maintain that the specification and claims as originally filed adequately support the claim language. *See, e.g.*, specification at page 7, line 29 to page 8, line 3; and page 13, line 29 through page 14, line 3. As described in the specification, for example at page 5, lines 1-3, GLP-1 agonists "refers to compounds that mimic the effects of GLP-1 on PCOS by binding to the receptor or receptors where GLP-1 causes its effect."

Although Applicants disagree, to facilitate prosecution, the independent claims 1, 12, 22, 32, 42, 52, and 62 have been amended to recite that the peptide compound is "capable of binding to and activating a GLP-1 receptor *in vivo*."

For the reasons set forth, Applicants respectfully request reconsideration and withdrawal of the written description rejection of claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 76, 78, 82, 84, 88, 90, 94, 96, 100, 102, 106, 108, and 112 under 35 U.S.C. §112, first paragraph.

III. Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 76, 78, 82, 84, 88, 90, 94, 96, 100, 102, 106, 108, and 112 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way so as to

enable those skilled in the art to make and/or use the invention commensurate in scope with the claims. Applicants respectfully disagree.

The Examiner admits that the specification is "enabling for the use of peptide compounds which are capable of binding to and activating a GLP-1 receptor in vivo," however, argues that the specification does not enable the use of "peptide compounds which are capable of binding to a GLP-1 receptor in vivo but which do not necessarily activate the receptor, i.e. which are GLP-1 antagonists." Office action at pages 3-4. Applicants respectfully traverse this rejection.

Applicants have provided considerable direction and guidance, and have presented working examples such that it is well within the level of ordinary skill in the art to practice the claimed invention without undue experimentation. For example, the specification discusses peptide compounds, including peptide mimetics, capable of binding to or activating a GLP-1 receptor. *See, e.g.,* specification, page 6, line 20 through page 9, line 27; page 11, line 22 through page 12, line 19; and page 16, line 5 through page 17, line 24. The specification also discusses GLP-1 receptors and methods for determining GLP-1 receptor binding or activation. *See, e.g.,* specification, page 10, lines 6-27. Taken in combination, such disclosure provides adequate direction to those skilled in the art of how to make and use the claimed invention.

Although Applicants disagree, to facilitate prosecution, the independent claims 1, 12, 22, 32, 42, 52, and 62 have been amended to recite that the peptide compound is "capable of binding to and activating a GLP-1 receptor *in vivo*." Accordingly, for at least these reasons, it is submitted that claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 76, 78, 82, 84, 88, 90, 94, 96, 100, 102, 106, 108, and 112 are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and reconsideration and withdrawal of this rejection is respectfully requested.

IV. Non-Statutory Double Patenting Rejection

Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 73, 75-79, 81-85, 87-91, 93-97, 99-103, 105-109, and 111-113 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/317,126. Applicants note that the rejection is provisional because no allegedly conflicting claims have been patented. Upon an indication of allowable subject matter,

a terminal disclaimer with regard to any issued claims in the '126 Application will be filed. At that time, withdrawal of this rejection is respectfully requested.

V. Statement of Common Ownership

Claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66, 72, 73, 75-79, 81-85, 87-91, 93-97, 99-103, 105-109, and 111-113 are allegedly "directed to an invention not patentably distinct from claims 1-18 of commonly assigned U.S. patent application 10/317,126," and "would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention of this application was made." Final Action at page 5. The Examiner asserts that "[a] showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e)." Initially, as discussed below, Applicants maintain that the presently pending independent claims are entitled to the benefit of the filing date of the parent applications.

The instant application and U.S. Application No. 10/317,126 were, at the time the invention of the instant application was made, owned by, or were subject to an obligation of assignment to, Amylin Pharmaceuticals. As such, U.S. Application Serial No. 10/317,126 is disqualified from being used in a rejection under 35 U.S.C. § 103(a) against the claims of the instant application. *See*, M.P.E.P. § 706.02(l)(2).

VI. Entitlement under 35 U.S.C. § 120 to the Benefit of Parent Application

Applicants acknowledge and thank the Examiner for indicating that claims 1-3, 5, 6, 12, 13, 15, 16, 22, 23, 25, 26, 32, 33, 35, 36, 42, 43, 45, 46, 52, 53, 55, 56, 62, 63, 65, 66, 72, 73, 75, 78, 79, 81, 84, 85, 87, 90, 91, 93, 96, 97, 99, 102, 103, 105, 108, 109, and 111 are entitled under 35 U.S.C. § 120 to the benefit of the filing date of parent application 10/317,126.

The Examiner maintains that "claims 4, 14, 24, 34, 44, 54, 64, 74, 76, 77, 80, 82, 83, 86, 88, 89, 92, 94, 95, 98, 100, 101, 104, 106, 107, 110, 112, and 113 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 10/317,126." Final Action at page 6. Applicants note that claims 77, 83, 89, 95, 101, 107, and 113 have been

cancelled without prejudice to or disclaimer of the underlying subject matter. As such, Applicants respond to the Examiner's arguments only as they pertain to claims 4, 14, 24, 34, 44, 54, 64, 74, 76, 80, 82, 86, 88, 92, 94, 98, 100, 104, 106, 110, and 112.[1]

As an initial matter, Applicants respectfully submit that the Patent Office has not met its burden to deny the priority of claims 4, 14, 24, 34, 44, 54, 64, 74, 76, 80, 82, 86, 88, 92, 94, 98, 100, 104, 106, 110, and 112 under 35 U.S.C. § 112. It is well established that the burden rests with the Patent Office to show that the requirements of 35 U.S.C. § 112 are not met. In particular, the Patent Office must provide specific reasoning why the application does not enable the scope of protection provided by the claims (*In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993)) and/or why persons skilled in the art would not recognize in the disclosure the invention defined by the claims (*Ex parte Sorenson*, 3 U.S.P.Q. 2d 1462 (B.P.A.I. 1987)). In the Office Action of June 7, 2005, it is stated that "disclosure of a few species does not provide support for the more generic claim terminology or for the other patentably distinct species currently claimed. The Federal Circuit has recently state that such blanket statements do not satisfy the Patent Office's burden under Section 112. *See, Capon v. Eshhar*, __F.3d. __, 2005 WL 1926027 (Fed. Cir., Aug 12, 2005).

Applicants respectfully maintain that the pending claims are fully supported under 35 U.S.C. § 112, first paragraph by the disclosure of parent application 10/317,126, as well as in provisional Application Serial No. 60/350,395 from which the parent application claims priority. At a minimum, *see, e.g.*, the disclosure at page 10, line 11 through page 14, line 28 of parent application 10/317,126 and pages 8 through 14 of provisional application 60/350,395. Taken in combination with the entirety of the disclosure of the parent applications, paragraph [0031] provides more than adequate disclosure of the subject matter of the present claims.

Further, Applicants respectfully traverse the Examiner's characterization of the disclosure of the parent applications, particularly with regard to exendin compounds. At a minimum, the parent applications disclose exendin peptides obtainable from Gila monster saliva, which were known in the art at the time of filing. *See, e.g.*, specification at page 13, line 9 through page 14,

[1] Applicants submit that cancelled claims 77, 83, 89, 95, 101, 107, and 113 are likewise entitled to the benefit of the filing date of 10/317,126.

line 12. In addition, numerous exendin analogs were known in the art as of the filing date of the 10/317,126 application. For example International Patent Application Publications WO 99/07404, WO 99/25727, WO 99/25728, which share common ownership with the instant application, disclose numerous exendin analogs. It is well established that, in the context of meeting the requirements of 35 U.S.C. 112, and specifically in the context of establishing a right to priority, the specification need not repeat and preferably omits that which is known in the art. *Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659 (Fed. Cir. 1986). This was recently reiterated that in assessing whether the requirements of Section 112 have been met the Patent Office must consider the scientific and technological knowledge already in existence, and specifically in the context of sequence information it is not necessary for the applicant to re-describe what is already known. *Capon v. Eshhar*, __F.3d. __, 2005 WL 1926027 (Fed. Cir., Aug 12, 2005).

Thus,"[i]t is well settled that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art." *In re Howarth*, 654 F.2d 103, 106 (CCPA 1981). In terms of written description, "[t]hat which is common and well known is as if it were written out in the patent and delineated in the drawings." *Webster Loom Co. v Higgins*, 105 U.S. 580, 586 (1881); see also, *Ex parte Wolters and Kuypers*, 214 USPQ 735, 736 (BPAI, 1979). In addition, the established rule of law is that an applicant can draw support for enablement from a pool of art which includes U.S. patents, and English-language textbooks and printed publications. *See In re Howarth*, 654 F.2d 103, 106 (CCPA 1981). Further, the Applicant need not cite the reference in the application, so long as the source of the information is such that persons skilled in the art would be able to locate the information with no more than reasonable diligence. *In re Howarth* at 107. As stated above, courts have already indicated the published patent literature is just such a source of information. *See*, *In re Howarth* at 106.

Additionally, the parent applications disclose GLP-1 receptor binding activity screening assays. *See, e.g.,* specification at page 15, lines 3-32. In addition, the parent applications disclose exendin-3 and exendin-4 sequences. *See, e.g.*, specification at page 13, lines 17-18. Taken in combination with the entirety of the disclosure of the parent applications, particularly with regard to agonists of the GLP-1 receptor, the parent applications disclose much more than

merely "a few species," as alleged by the Examiner. Applicants respectfully submit that the specification adequately describes the genus of exendin peptides.

In any event, whatever else the parent applications do disclose, the presently pending claims are clearly supported under 35 U.S.C. § 112, first paragraph by the disclosure of the parent applications. As such, it is respectfully submitted that claims 4, 14, 24, 34, 44, 54, 64, 74, 76, 80, 82, 86, 88, 92, 94, 98, 100, 104, 106, 110, and 112 are entitled to the benefit of the filing date of the parent applications.

VII. Rejections Under 35 U.S.C. § 102

A. U.S. Patent Application Publication 2004/0029784

Claims 4, 14, 24, 34, 44, 54, 64, 76, 77, 82, 83, 88, 89, 94, 95, 100, 101, 106, 107, 112, and 113 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication 2004/0029784 (hereinafter the "'784 Publication"), which is the publication of U.S. Patent Application Serial No. 10/317,126. This rejection is respectfully traversed. As discussed above, the presently pending claims are entitled to the benefit of the filing date of the parent applications, and as such, the '784 Publication does not constitute prior art under 35 USC § 102(e). Further, even if the dependent claims were not entitled to the benefit of the parent applications, which Applicants do not concede, then likewise, the parent application does not anticipate such subject matter because anticipation requires disclosure of each and every element. Accordingly, withdrawal of this rejection is respectfully requested.

B. Knudsen

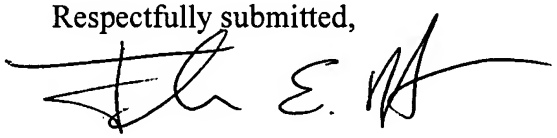
Claims 4, 14, 76, 77, 82 and 83 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Knudsen (U.S. Patent Application Publication 2004/0180824). This rejection is respectfully traversed, and to the extent that it applies to the amended claims, reconsideration is requested for at least the reasons that follow. Again, as discussed above, the presently pending claims are entitled to the benefit of the filing date of the 60/350,395 application. As such, Knudsen does not constitute prior art under 35 USC § 102(e).

Accordingly, for at least the foregoing reasons, the rejection of claims 4, 14, 24, 34, 44, 54, 64, 76, 77, 82, 83, 88, 89, 94, 95, 100, 101, 106, 107, 112, and 113 under 35 U.S.C. § 102(e) is traversed. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5085 should any additional information be necessary for allowance.

Respectfully submitted,



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